Attachment 1 K070077

510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical
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Contact person: Villy Braender, Regulatory Manager
Date prepared: 5 January 2007

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Trade name: Ultrasound Scanner ProFocus 2202
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1550)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
Siemens Medical Solutions USA Inc: Acuson CV70 Cardiovascular system (K032111)

Device description:

2202 supports the following scanning modes and combinations thereof:
B-mode, M-mode, CWD-mode, PWD mode and CFM mode. Tissue harmonic imaging, Contrast harmonic imaging.
An optional ECG signal can be superimposed the ultrasound information in all modes and mode combinations.
An optional 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.
The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.

Transducers
Transducers are linear and convex phased arrays and mechanical sector.
The patient contact materials comply with ISO10993-1
All transducers used together with 2202 are Track 3 transducers.

Acoustic output
The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI ≤ 6.0

Clinical measurement accuracy.
Clinical measurements and calculations are described and accuracies are provided with the User Guide.

Thermal, mechanical and electrical safety.
The scanner 2202 has been tested by a recognized, certified body according to IEC 60601-1.

Attachment 1

Acoustic Output Reporting

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"

The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (AIUM 1998).

Intended use.

See comparison below

Technological characteristics compared to the predicate device.

The predicate device has the same major technological characteristics as the subject device, see comparison below.

Comparison with Siemens Medical Solutions USA Inc: Acuson CV70 Cardiovascular system (K032111)

	ProFocus 2202 in this application	K032111
Intended uses	Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics, Transrectal, Small organs, Transvaginal, Musculoskeletal (superficial, conventional), Peripheral Vascular. **Transcranial (Adult cephalic)** Measurements and calculations	Abdominal. Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Transesophageal. Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. Measurements and analysis
General device description	Track 3 (Index display). Scanning modes and mode combinations: B, B+M, B+CWD, B+D, B+C, B+D+C. (CWD is continuous wave Doppler, D is PWD, C is Color Flow mapping Doppler including Velocity+Variance display, Amplitude (power) Doppler. B mode includes Tissue Harmonic Imaging (THI) and Contrast Harmonic Imaging (CHI). 3D imaging	Track 3 (Index display) B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of **modes,** or Harmonic Imaging, or 3D imaging
Acoustic output	Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic). TI ≤ 6.0	Not in 510(k)summary, except that it has index display according to Display standard.
General safety and effectiveness	AIUM/NEMA UD-3 AIUM/NEMA UD-2	UL 2601-1 CSA C22.2 No. 601-1 AIUM/NEMA UD-3 AIUM/NEMA UD-2

	93/42/EEC Medical Devices Directive, EN/IEC 60601-1 EN/IEC 60601-1-1 EN/IEC 60601-1-2 EN/IEC 60601-2-37 EN/ISO 10993-1	93/42/EEC Medical Devices Directive EN/IEC 60601-1 EN/IEC 60601-1-1 EN/IEC 60601-1-2 IEC 1157 IS0 10993
Labeling	Please refer to section 4.8	Not in 510(k) summary)

Conclusion: The device ProFocus 2202 in this application has similar intended uses, and in particular the subject for the application **Transcranial (Adult cephalic)**, is the same.

B-K Medical ApS therefore believes, that 2202 is substantially equivalent to K032111.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Villy Brænder
Official Correspondent
B-K Medical
Mileparken 34, DK-2730 Herlev
DENMARK

MAR 0 5 2007

Re: K070077
Trade Name: Ultrasound Scanner Profocus 2202
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulations Name: Ultrasound pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: January 5, 2007
Received: January 10, 2007

Dear Mr. Brænder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner Profocus 2202, as described in your premarket notification:

Transducer Model Number

8827

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K070077

Device Name: **Ultrasound Scanner Profocus 2202**

Indications For Use:

Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD,CWD, Color Doppler and combined mode imaging.
Guidance of biopsy needles, geometrical measurements and calculation of parameters.
Non monitoring ECG for superimposing the ultrasound information.
An optional 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

Clinical applications: Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics, Transcranial (=Adult cephalic),Transrectal, Small organs, Transvaginal, Musculoskeletal.

Details on specific Indication for Use forms

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of _____

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070077

Diagnostic Ultrasound Indications for Use Form

System: 2202 K070077

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	Tissue- and contrast harmonic imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify 1)	Continous Wave)
Ophthalmic										
Fetal		P	P	P	P	P	P		P	
Abdominal		P	P	P	P	P	P		P	
Intraoperative (specify)		P	P	P	P	P	P		P	
Intraoperative Neurological		P	P	P	P	P	P		P	
Pediatric		P	P	P	P	P	P		P	
Small Organ (specify)		P	P	P	P	P	P		P	
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N	N
Cardiac		P	P	P	P	P	P		P	N
Transesophageal										
Transrectal		P	P	P	P	P	P		P	
Transvaginal		P	P	P	P	P	P		P	
Transurethral		P	P	P	P	P	P		P	
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		P	
Musculo-skeletal Superficial		P	P	P	P	P	P		P	
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 1) B+M, B+D, B+C, B+D+C. B mode includes Tissue-and Contrast Harmonic Imaging. D is PWD, C is Color Doppler. Fetal is often called Obstetrics

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K070077

Diagnostic Ultrasound Indications for Use Form

System: 2202

Transducer 8827 K070077

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	**Mode** of Operation									
	A	B	M	PWD	Tissue- and contrast harmonic imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify 1)	Continous Wave CW
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N	N
Cardiac		E	E	E	E	E	E		E	N
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 1) B+M, B+D, B+CW, B+C, B+D+C. B mode includes Tissue-and Contrast Harmonic Imaging. D is PWD, C is Color Doppler. Fetal is often called Obstetrics

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K070077